Syaloset 64mg/4ml

Hyaluronic acid of biotechnological origin

Made in the European Union

Intra-articular use

Increased effectiveness and tolerability

Safety of use

RIVER PHARMA

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Syaloset 64mg/4ml

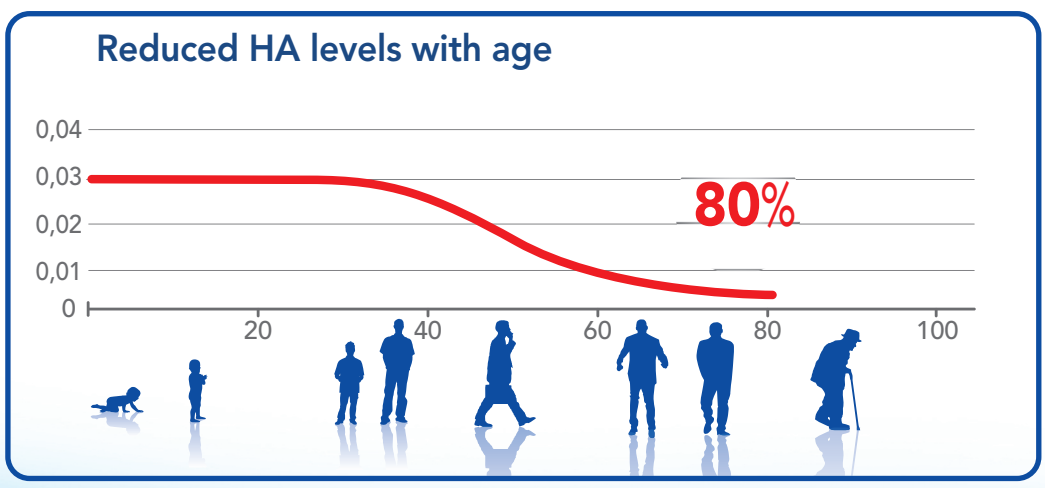
Intra-articular injection, improves the physiological and rheological conditions of arthritic joints and tissues by increasing flexibility and reducing impact-related traumas.

Advantages

- *It provides a double dose (64 mg/4ml) compared to similar preparations*
- *It comes in 5 ml vials and a 5 ml syringe*
- *The Doctor can associate it to other Substances*

HA is a natural organic compound, synthesized by fibroblasts, that contains repetitive sequences of **glucuronic acid** and **N-acetylglucosamine**

- *High degree of purity*
- *Optimal molecular weight (800-1.200 kDalton)*
- *High kinematic viscosity*

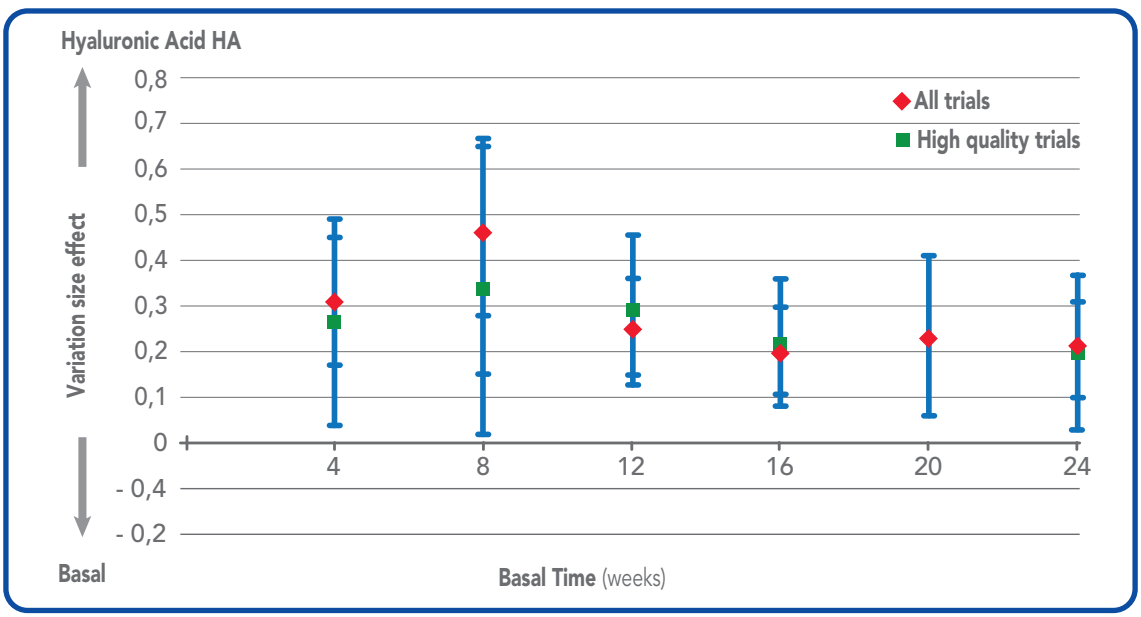


After 45 years of age or traumas, the HA levels decrease in a progressive manner, therefore reducing the viscosity of synovial fluids, which will no longer be able to protect articulation from friction. This causes cartilage deterioration resulting in consequent inflammations and pain.

Properties

- *Improves the viscosity of synovial fluids and reduces joint pain*
- *Improves patient mobility while inducing a prolonged analgesic effect*
- *Counteracts the degeneration process of Articular Cartilage and promotes repair*
- *Results seen after 2 infiltrations per cycle of treatment*

The HA intra-articular therapy is effective after the 4th week and reaches its peak on the 8th week; this effect lasts for 24 weeks



Meta-analysis of 54 studies on 7.545 patients with knee OA

This is a medical device CE 0373

1 5 ml vial containing 4 ml of Hyaluronic Acid HA 1.6% = 64 mg

1 sterile syringe

*Dosage: **2 infiltration /T°0-T°1 = 15 days***

***6 months** of therapeutic effectiveness*

Syaloset — Sodium hyaluronate solution 1.6% - 64 mg/4 ml

DESCRIPTION

Syaloset is a medical preparation with viscoelastic properties made up of a sterile, non-pyrogenic and isotonic solution of highly purified hyaluronic acid sodium salt obtained by fermentation without chemical modification processes.
Syaloset does not contain avian proteins (chicken derivatives) and therefore does not present the risk of causing allergic reactions due to these components and guarantees perfect tolerability and safety when used. The hyaluronic acid used in **Syaloset** conforms with the European Pharmacopoeia guaranteeing the purity and stability of the product.
Injected directly into the joint **Syaloset** exerts a viscosupplementary action improving the lubricant and shock absorbent properties of the synovial fluid.
Syaloset is a new generation product which when administered "renews the viscosity" of the synovial fluid, enabling a return to normal activity.

DETAILED DESCRIPTION:

Syaloset is viscoelastic preparation made up of 4ml of a sterile non-pyrogenic isotonic solution containing 1.6% of highly purified hyaluronic acid obtained by bacterial fermentation from a high molecular weight fraction (> 1,700,000 Daltons)
The medical preparation is contained in a single use 5ml phial containing 64mg of hyaluronic acid accompanied by a 5ml syringe with individual sterile protection (medical device class Is CE 0123)
Composition per ml:

Sodium hyaluronate:	16mg
Sodium chloride:	8.5mg
Dibasic sodium phosphate dihydrate	0.563 mg
Monobasic sodium phosphate monohydrate	0.0045 mg

Water for injectable preparations.
Syaloset is manufactured in a terminally sterilised aseptic environment.
Hyaluronic acid sodium salt is formed of repeated chains of disaccharide N-acetylGlucosamine and sodium Glucuronate units. It is a fundamental component of synovial fluid to which it gives its particular viscoelastic properties.

INDICATIONS

Syaloset is a substitute for synovial fluid for patients affected by degenerative or mechanical arthropathy, making it possible to renew the physiological and rheological properties of the arthritic joints. It reduces pain and re-establishes the joint's movement by substituting or supplementing the elastoviscosity of the synovial fluid of the arthritic joints.In the case of particular pain or reduced mobility due to degenerative diseases, post-traumatic problems or due to alterations to the knee joints or other synovial joints.
Syaloset exerts this therapeutic action thanks to the special characteristics of the hyaluronic acid sodium salt used which is obtained by fermentation, not chemically modified, and with high tolerability. **Syaloset** only acts on the joint it is injected into, without exerting any systematic action.

DOSAGE AND ADMINISTRATION

Aspirate any joint effusion before proceeding with the injection of **Syaloset**. Insert a sterile 18 G diameter needle in the syringe. Screw the needle firmly to the neck of the syringe to ensure an airtight seal then draw up the sterile hyaluronic acid solution from the phial. Substitute the needle with a suitable (21 G) sterile needle and screw it firmly to the neck of the syringe to ensure an airtight seal and prevent spillage of the liquid during administration and then inject the **Syaloset** into the arthritic joint. Only inject **Syaloset** within the synovial space. The 4ml dose is indicated for knee and hip joints. For all other joints it is advisable to inject a reduced amount in relation to the capacity of the joint.
It is advisable to repeat knee treatment after 3-6 weeks in order to achieve long term improvement of the symptoms.
The validity and frequency of the treatment cycle must be assessed by the doctor for each individual patient, in each case taking into account the risk/benefit ratio of the treatment.
For the hip joint it is advised to inject the product with ultrasound guidance.

Warning: administration of the product must only be effectuated by specialist doctors.
All the regulations concerning asepsis and injection techniques must be carefully observed.
If there is any joint effusion it must be removed prior to administration of the product.

PRECAUTIONS

Do not mix **Syaloset** with disinfectants containing quaternary ammonium salts, or chlorhexidine because hyaluronic acid can precipitate in their presence.
Avoid the concomitant administration of **Syaloset** with other products for intra-articular use in order to prevent any possible interaction.

WARNINGS

The content of the phial is sterile. The syringe is in a sealed blister pack.
The exterior surface of the syringe's blister is not sterile.
Do not use **Syaloset** after the expiry date on the package.
Do not use **Syaloset** if the packaging is damaged.
The medicine is for single use only and the contents must be used immediately on being drawn from the phial after removing any air bubbles.
The injection entry point must be on healthy skin. Not for vascular injection.
Do not inject externally to the articular cavity, in the synovial tissue or in the articular capsule.
Do not administer **Syaloset** if there is abundant intra-articular effusion.
Store at room temperature and always below 25°C and away from heat sources.
Do not freeze. Once the **Syaloset** phial has been opened the contents must be used immediately and disposed of after use. After the intra-articular injection the patient is advised to avoid any strenuous physical activity and only go back to normal activity after a few days. There is not yet any information about the safety and effectiveness of **Syaloset** in pregnant women, nursing mothers, and children.
Keep out of reach of children.

INTERACTIONS

No known interactions between **Syaloset** and other drugs at this stage.

SIDE EFFECTS

Infiltration with **Syaloset** may cause localised side effects. During the use of**Syaloset** the following symptoms may appear around the injection site: pain, heat, redness or swelling. These secondary effects may be alleviated by applying ice to the treated joint.
These symptoms will normally disappear after a short period. The doctor must ensure that patients inform him of any adverse effects occurring after treatment.

CONTRAINDICATIONS

Syaloset must not be injected if the joint is infected or seriously inflamed or if the patient has a skin infection or other problem in in the area where the injection is to be made.
Syaloset must be administered with caution in patients with diabetes or affected by chronic pathologies.
ONY AVAILABLE WITH A PRESCRIPTION.
ONLY A DOCTOR CAN ADMINISTER THE INTRA-ARTICULAR INJECTION.

HOW SUPPLIED

The package contains 1 sterile phial containing 64mg of hyaluronic acid sodium salt in 4ml of buffered physiological sodium chloride solution, with 1 syringe in a sterile package (Medical device class Is CE 0123).

EXCLUSIVE DISTRIBUTOR

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